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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/254,288	04/02/1999	WOLFGANG TESCHNER	040433/0177	6758

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EXAMINER	
MARX, IRENE	

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 07/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/254,288	TESCHNER ET AL.	
	Examiner	Art Unit	
	Irene Marx	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *14-18,20-31 and 33-37* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-18, 20-31 and 33-37* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/24/04 has been entered.

Claims 14-18, 20-31 and 33-37 are being considered on the merits.

Claim Rejections - 35 USC § 112

INDEFINITE

Claims 14-18, 20-31, and 33-37 are/remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 14 and 31 are vague and indefinite in that the extent of the "replacing" is not claim designated and cannot be readily ascertained. Is it 1%, 10%, 80%, 100%? In other words, is it "total replacement"? Is the medicament produced citrate-free?

As noted previously, the first Teschner Declaration raises issues of confusion regarding the definition and meaning of "non-precipitating conditions" in the present context. The first Teschner Declaration at item 5 states that the conditions are "non-precipitating conditions through diafiltration, ultrafiltration or a chromatographic process", which clearly defines the invention intended. Yet the claims are written are devoid of this limitation. It is recommended that this material be claim designated to clarify the invention. Applicants failed to address this issue.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 31 and 33-34 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ristol Debart *et al.*

The claims are drawn to a plasma-protein containing medicament made from citrate plasma or a citrate-containing plasma fraction which contains less than 100 μg/l of metals such as aluminum and which does not take up any undesired metals when stored in metal-containing containers..

The cited reference discloses a plasma-protein containing medicament made from citrate plasma or a citrate-containing plasma fraction which contains less than 100 parts per billion of metals such as aluminum and which does not take up any undesired metals when stored in metal-containing containers. See, e.g., col. 3-4. The referenced medicament appears to be identical to the presently claimed medicament and is considered to anticipate the claimed medicament since it is disclosed as having the same property of having the same amount of less than 100 μg/l of metals. Consequently, the claimed medicament appears to be anticipated by the reference.

In the alternative, even if the claimed medicament is not identical to the referenced medicament with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced medicament is likely to intrinsically possess the same characteristics of the claimed medicament particularly in view of the similar characteristics which they have been shown to share. Thus the claimed medicament would have been obvious to those skilled in the art within the meaning of USC 103.

Furthermore, the medicament is claimed as a product-by-process. Since the Patent and Trademark Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make comparisons therewith, a lesser burden of proof is required to make out a case of prima facie obviousness for product-by-process claims because of their peculiar nature than when a product is claimed in the conventional manner. MPEP 2113.

Accordingly, the claimed invention as a whole was at least prima facie obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 14-17, 20-23, 26, 28, 31, and 33-37 are/remain rejected under 35 U.S.C. 102(e) as being clearly anticipated by US 5561115 [A] for the reasons as stated in the last Office action and the further reasons below.

Response to Arguments

Applicant's arguments and the second Teschner declaration filed 5/17/04 have been fully considered but they are not persuasive.

The arguments in the Teschner declaration indicate that the conditions of '115 are the same as those in EP 893450 ('450) are noted. In the declaration, Applicant now states that 0.04-0.08 M are denaturing conditions. However, the specification, page 9, clearly implies that this amount is well within the claimed invention, since a range of 1.0 mmol to 1.5 mol/l is indicated as suitable for the as filed specification, with narrower preferred ranges indicated.. The range of 1.0 mmol to 1.5 mol/l clearly encompasses the amount of caprylate used in the reference, i.e. the amounts encompassed in the application are not lower than those of the reference as alleged (Item 10). There is no clear definition in the as filed specification for the amounts or conditions intended to be suitable to constitute "non-precipitating conditions" for all monocarboxylates and dicarboxylates as claimed. Replacement of functional language with appropriate ranges that provide the touted results might advance prosecution. No new matter may be added. Moreover, it is apparent that the "replacement" of citrate is envisioned in conjunction with diafiltration, ultrafiltration or a chromatographic process etc.. This material should also be part of the invention as claimed.

Therefore, the arguments in the declaration are not persuasive. Accordingly, the rejection is deemed proper and it is adhered to.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (571) 272-0919. The examiner can normally be reached on M-F (6:30-3:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on (571) 272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Irene Marx
Primary Examiner
Art Unit 1651